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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/624,735	07/21/2003	Robin C. Whitmore	CRANIO-42318	7156
45200	7590	08/11/2006	EXAMINER	
PRESTON GATES & ELLIS LLP 1900 MAIN STREET, SUITE 600 IRVINE, CA 92614-7319			COMSTOCK, DAVID C	
			ART UNIT	PAPER NUMBER

3733

DATE MAILED: 08/11/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/624,735

Applicant(s)

WHITMORE ET AL.

Examiner

David Comstock

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 May 2006.
2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 1-16 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☒ The drawing(s) filed on 21 July 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Petition under 37 CFR 1.91

The petition submitted under 37 CFR 1.91(3) has been considered but is not persuasive. It is noted that the photographs are not necessary to understand Applicant's invention. Furthermore, patentability does not depend on what is shown in the photographs, but rather, that which is positively recited in the claims.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Okada et al. (4,323,326) in view of Schwartzman et al. (4,125,050).

Okada et al. disclose a self-drilling screw 1 comprising a body having a head at one end and a tip at the other end, and dual-lead threads 6 and 7, respectively (see, e.g., Fig. 5. The dual-lead threads 6,7 taper (as about 5) toward the cutting tip where the pitch, i.e. the distance between threads, widens. In the opposite direction, toward the head, the threads transition to a more straight configuration (see, e.g., Fig. 5). The screw has a constant root diameter along the entire "parallel portion" 2 of the shank. The threads have a rake angle. Okada et al. do not disclose a single flat cutting edge

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extending generally perpendicular to a central longitudinal axis of the body.

Schwartzman et al. disclose a self-drilling screw 10 having an angled cutting tip similar to Okada et al., and in addition, a single, flat, transverse cutting tip 38 at an extreme end in order to substantially reduce the friction and drag on the entire drilling point and to help the screw to stabilize quickly and have little or no tendency to walk during the starting of the drilling operation (see Figs. 1 and 2 and col. 2, lines 4-11). It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the screw of Okada et al. with a single, flat, transverse cutting tip, in view of Schwartzman et al., in order to substantially reduce the friction and drag on the entire drilling point and to help the screw to stabilize quickly and have little or no tendency to walk during the starting of the drilling operation. It would have been further obvious to provide the head with a recess, since it is old and well-known in the fastener art to provide heads with recesses in order to engage a driving tool and facilitate the application of torque to the screw (as evidenced by, e.g., Whitesell, 5,356,253, col. 2, lines 38-41). It also would have been obvious to form the screw of titanium alloy, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416. It is noted that titanium alloy is a well-known material and is suitable as a fastener due to, for example, its strength, light weight, and non-reactivity or resistance to rust. It also would have been obvious to form the screw to have a diameter of approximately 1.0 to 2.0 mm and a length of approximately 3.0 to 6.0 mm, since it has been held that where the general conditions of a claim are

disclosed in the prior art, a screw having a diameter and a length, discovering the optimum or workable ranges of these dimensions involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

Response to Arguments

Applicant's arguments have been fully considered but they are not persuasive. Applicant's arguments that the tip of the screw shown in Schwartzman et al. is allegedly not flat is without merit. The edge 38 of the tip 40 is manifestly a single, flat edge, perpendicular to the longitudinal axis of the screw, as can be clearly seen in Figs. 2 and 3. Indeed, as stated by Applicant on page 7 of the Remarks, "The depiction of the self-drilling screw of Schwartzman et al. in Figure 3 is confirmed by the description of the cutting tip in column 3 lines 1-6." The "edge" (singular) 38 is formed on the distal end of and defined by the "interconnecting web" 40. Perhaps applicant is relying on the offset nature of the cutting edges 34; however, it is the edge 38 defined on the web 40 interconnecting the cutting edges 34 that satisfies the claims and is being relied upon. Edge 38 is straight and level, perpendicular to the longitudinal axis of the screw, not inclined, not curved, not discontinuous, etc., and there is no valid reason for alleging that it somehow does not satisfy the claim language.

Conclusion

All claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.114 and could have been finally rejected on the

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grounds and art of record in the next Office action if they had been entered in the application prior to entry under 37 CFR 1.114. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action after the filing of a request for continued examination and the submission under 37 CFR 1.114. See MPEP § 706.07(b).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Comstock whose telephone number is (571) 272-4710. Please leave a detailed voice message if examiner is unavailable. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached at (571) 272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



D. Comstock



EDUARDO C. ROBERT
SUPERVISORY PATENT EXAMINER